K090190

NUCLEMED

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510(K) SUMMARY

OCT - 9 2009

WIN-NEUS ™

Date: July 14th, 2009

Submitter:
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Device Names:

Trade Name: *WIN-NEUS ™ Stereotactic Surgery Treatment Planning System*
Common Name: *Stereotaxic Instrument*
Classification Name: *Instrument, Stereotaxic*

Legally Marketed Device to Which Substantial Equivalence is Claimed:

The WIN-NEUS ™ unit is *substantially equivalent (SE) to Leksell SurgiPlan (K033340) cleared in 2004.

*Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation [42 Fed. Reg. 42,520 et seq. (1977)].

Device Description:

WIN-NEUS ™ is planning system software for brain Stereotactic Surgery. The user can load image patient studies from different image modalities (CT, MRI, etc) with or without fiducials, register them and define a variety of image fusions among them. A brain Atlas and tools for image segmentation are also available. Image reconstructions in axial, coronal and sagital planes can be used along with image reconstruction in planes along and orthogonal to the proposed track to avoid probe intersection with critical structures or vessels. Win-NEUS is a powerful tool for Stereotactic Surgery such as biopsies and treatment of Parkinson disease.

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510(K) SUMMARY (CONTINUED)

WIN-NEUS ™

Stereotactic system definition (stereotactic frame and arc) is input information for the software. Other input information is images studies from the patient of different modalities. At least the reference image study has to be taken with the stereotactic frame in place and with fiducials. Fiducials are used to register the image study against the virtual space defined by the stereotactic frame already inputted at the system. Additional or auxiliary image studies can be registered either with fiducials or co-registered against previously registered image studies without using fiducials.

Once image studies have been registered, a correspondence between coordinates defined on the esterotactic frame in the real patient and points in images displayed by the software are established.

After registering images against the stereotactic frame the user can proceed to plan the stereotactic surgical procedure. He can use images to identify anatomical structures and determine the target, which is the point where the surgeon wants to take the biopsy or wants to locate the tip of a catheter for example. Afterwards the user has to decide the track, which is the intersection of the needle or catheter with the patient in order to avoid critical structures. The software will display image reconstructions with the position of the proposed track superimposed, so that the user can choose the better track.

The Output of the software are the target coordinates to be set on the stereotactic frame and angles to be set on the stereotactic arc for the surgeon to reach the chosen target with the chosen track.

Indications For Use:

WIN-NEUS ™ is planning system software for brain Stereotactic surgery such as biopsies and treatment of Parkinson disease. The WIN-NEUS ™ is intended to be used with Leksell Coordinate G Frame and Leksell Multi Purpose Stereotactic Arc systems.

Technological Characteristics Comparison to Predicate Device:

The proposed device was compared to the predicate devices as described in section 9 of this submission. All of the items contained in the tables of section 9 have been found to be substantially equivalent.

Performance Data:

The proposed device's performance was compared to the predicate device's performance as described in section 10 of this submission. All of the items contained in the tables of section 10 have been found to be substantially equivalent.

FOIA: The submission associated with this summary contains FOIA exempt voluntary information concerning the applicant's commercial and/or financial goals and trade secrets. This information is privileged and confidential and is exempt from public disclosure in accordance to FOIA Exemption 4, 21 CFR 20.61, and the "Trade Secrets Act" of Exemption 3. Applicant requests the "Right to Reverse" any FOIA action regarding the submission and a chance to redact the submission's contents as appropriate. Applicant requests a consultation prior to any FOIA release under the provisions in 21 CFR 20 and sections affording similar rights. This 510(k) summary is suitable for public disclosure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Nuclemed S.A.
c/o Mr. Raymond Kelly, Arazy Group
56B Shadowbrook Dr.
Hudson, New Hampshire 03051

OCT - 9 2009

Re: K090190
Trade/Device Name: WIN-NEUS Stereotactic Surgery Treatment Planning System
Regulation Number: 21 CFR 882.4560
Regulation Name: Instrument, Stereotaxic
Regulatory Class: Class II
Product Code: HAW
Dated: August 11, 2009
Received: August 11, 2009

Dear Mr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K090190

Device Name: **WIN-NEUS™**

Indications For Use:

WIN-NEUS ™ is planning system software for brain Stereotactic surgery such as biopsies and treatment of Parkinson disease. The WIN-NEUS ™ is intended to be used with Leksell Coordinate G Frame and Leksell Multi Purpose Stereotactic Arc systems.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Prescription Use ✓
(Per 21 CFR 801.109)

510(k) Number K090190